

REMARKS

The Office Action of July 31, 2007, has been received and reviewed. Claims 1-13 and 15-21 are currently pending in the application. Claims 1-13, 16-19, and 21 stand rejected. Claim 21 is amended herein. All amendments are made without prejudice or disclaimer. No new matter has been presented. Reconsideration is respectfully requested.

Rejection under 35 U.S.C. § 112, Second Paragraph

Claim 21 stands rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite. Specifically, claim 21 recites “the polynucleotide of SEQ ID NO:2” although SEQ ID NO:2 is properly a polypeptide. Applicants respectfully submit that appropriate correction has been made.

Rejections under 35 U.S.C. § 103(a)

Claims 1-13 and 16-19 stand rejected under 35 U.S.C. § 103(a) as assertedly being obvious over Theodoulou (Biochem. Biophys. Acta 1465 79-103) (hereinafter “Theodoulou”) in view of Dudler *et al.* (J. Biol. Chem. 267:9 5582-5588) (hereinafter “Dudler”) and in further view of Sidler *et al.* (The Plant Cell, Oct. 1998; Vol. 10, 1623-1636) (hereinafter “Sidler”) (hereinafter collectively “the references”). Applicants respectfully traverse the rejection as hereinafter set forth.

Applicants note that to establish a *prima facie* case of obviousness the prior art reference (or references when combined) must teach or suggest all the claim elements. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974); *see also* MPEP § 2143.03. Additionally, there must be “a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements” in the manner claimed. *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742, 167 L.Ed.2d 705, 75 USLW 4289, 82 U.S.P.Q.2d 1385 (2007). Finally, to establish a *prima facie* case of obviousness there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Furthermore, the reason that would have prompted the combination and the reasonable expectation of success must be found in the prior art, common knowledge, or the nature of the problem itself, and not based on the Applicant’s disclosure. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1367

(Fed. Cir. 2006); MPEP § 2144. Underlying the obvious determination is the fact that statutorily prohibited hindsight cannot be used. *KSR*, 127 S.Ct. at 1742; *DyStar*, 464 F.3d at 1367.

Applicants respectfully submit that the claims cannot be obvious over the references as the references do not teach or suggest each and every claim element. Specifically, the independent claims (1, 7, 10, 12, and 16) each recite “wherein said ABC-transporter functions to transport at least one secondary metabolite in plant cells.” Applicants note that the references do not teach the exact function of the ABC transporter being discussed (AtPGP1). At best, the authors of the references suggest that AtPGP1 might be involved in the export of signal compound, possibly a peptide hormone. Theodoulou at page 86, first full paragraph. Applicants note that there is no suggestion in the references that the signal compound, which might be a peptide hormone, is a secondary metabolite. Indeed, given its role in promoting hypocotyl cell elongation (as discussed in Sidler), applicants submit that any molecule transported by AtPGP1 is likely a primary metabolite. Applicants further note that none of the antisense constructs of Sidler were complete knockouts of AtPGP1 production (*see* FIG. 1). This strongly suggests that at least some production is required for plant survival, and thus involved in a primary metabolite pathway. As such, applicants respectfully submit that the references do not teach “wherein said ABC-transporter functions to transport at least one secondary metabolite in plant cells” as it has not been shown what AtPGP1 transports, if it transports anything at all.

Applicants further note that claim 1 recites “selecting transformed plant cells having an induced or enhanced production or secretion of at least one secondary metabolite;” claim 7 recites “selecting transformed plants based upon enhanced production of secondary metabolites;” and claim 16 recites “selecting transformed plant cells exhibiting enhanced transport of said at least one secondary metabolite into a vacuole.” Applicants respectfully submit that the references do not teach selecting the transformed cells by any of the criteria provided for in these claims. Theodolou is a review article and provides no teaching of how to select transformed cells based on production or location of transport. Sidler teaches the selection of transgenic plants by kanamycin resistance (page 1634, column 1, 1st paragraph). Dudler teaches the isolation of the AtPGP gene, but never produces cells expressing the gene and therefore engages in no selection of transformed cells. As such, applicants respectfully submit that the references do not teach selecting transformed cells based on production or location of transport.

Taken together, it appears to applicants that the Examiner is asserting that the prior art suggests that secondary metabolites might be substrates of ABC transporters, that these transporters might transport secondary metabolites and that, as such, secondary metabolites might have something to do with the compartmentation and synthesis of secondary metabolites. However, applicants respectfully submit there is not a single demonstration or a suggestion in the art which teaches a skilled person that, in order to obtain increased production of secondary metabolites in a plant, it suffices to transform the plant with an ABC transporter. Restated, there is no teaching or suggestion that pumping-out secondary metabolites will obviously result in their increased production. Applicants note that secondary metabolites are often toxic for plants. However, it has not been demonstrated or suggested that removing toxic compounds via ABC transporters will result in a higher production of such toxic compounds.

In addition, applicants respectfully submit that proper weight has not been given to the Declaration of Alain Goossens. One of skill in the art would understand that statements such as “suggests a role of plant P-gp in synthesis and compartmentation of [secondary metabolites]” are wide ranging statements that provide the proteins some role. Theodoulou, page 86, column 2, first paragraph. However, one of skill in the art would also understand that a definite and clear distinction exists between a suggested role in synthesis and compartmentation of a compound and being capable of enhancing or stimulating the production or secretion of that compound. For example, the evidence presented in the Declaration shows that 3 genes known to be involved in the synthesis and/or compartmentation of a secondary metabolite had no ability to enhance production or secretion of that secondary metabolite. The Declaration provides 17 other examples of genes that one could easily suggest have a role in the synthesis and compartmentation of a secondary metabolite, but have no ability to enhance production or secretion of that secondary metabolite when actually tested. Thus, as would be understood by one of skill in the art, the possibility of a gene being involved in the synthesis and/or compartmentation of a secondary metabolite does not translate into reasonable probability of that gene being able to enhance or stimulate the production or secretion as genes known to be involved in the synthesis and/or compartmentation of a secondary metabolite do not have such a function. It is for these reasons, *inter alia*, that the one of ordinary skill in the art would have no reasonable expectation of success and why the presently claimed methods provided unexpected

results.

It is axiomatic that the declaration “is evidence that must be considered.” *MPEP 2164.05* (2004)(providing that Declarations must be considered). Applicants respectfully submit that the Examiner has not properly weighed the evidentiary value of the Goossens Declaration, it has been dismissed as not being drawn to any of the species falling with in the claimed genus of ABC transporters. However, as explained above, Goossens Declaration relates to the notion of ABC transporters being directly coupled to production and secretion levels of secondary metabolites, to which the claimed methods are directed.

Further, the Goossens Declaration makes clear statements regarding unexpected results and lack of reasonable expectation of success in view of the evidence presented. The Examiner has provided no evidence to contradict the Goossens Declaration. The 2001 case of *In re Zurko* clearly states that the Examiner (and the Board) must make its findings based upon the written record. See 59 USPQ2d 1693, 1697 (Fed. Cir. 2001). Here, the written record consists of the Goossens Declaration and its provided evidence. The Examiner has produced nothing to refute applicants’ evidence other than to indicate that it was considered irrelevant. Accordingly, Applicants request that the Examiner accept the Goossens Declaration as evidence that the presently claimed methods provide unexpected results and establishes a lack of reasonable expectation of success.

For at least the foregoing reasons, applicants respectfully request the withdrawal of the rejections of claims 1-13 and 16-19 under 35 U.S.C. § 103(a) and reconsideration of same.

ENTRY OF AMENDMENTS

Pursuant to 37 C.F.R. § 1.116, applicants respectfully submit that the amendments presented herein should be entered as the amendments are made to expedite prosecution, are believed to remove issues for appeal, and place the application in condition for allowance.

Applicants respectfully note that, as indicated at MPEP § 714.13(III), the Examiner is required to give the proposed amendments sufficient consideration to determine whether the claims are in condition for allowance and/or whether the issues on appeal are simplified. Applicants respectfully submit that the amendments avoid the rejections set forth in the Final Office Action, raise no issues of new matter, present no issues requiring further consideration or

search, and do not present any additional claims. If the Examiner determines that the amendments do not place the application in condition for allowance, entry is respectfully requested as they remove issues for appeal. As such, the applicants respectfully request that the amendments presented herein be entered and a Notice of Allowance issued.

CONCLUSION

In light of the above amendments and remarks, applicants respectfully request reconsideration of the application. If questions remain after consideration of the foregoing, or if the Office should determine that there are additional issues which might be resolved by a telephone conference, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



Daniel J. Morath, Ph.D.
Registration No. 55,896
Attorney for Applicants
TRASKBRITT, P.C.
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

Date: September 28, 2007
DJM/djm